510 (K) Summary
Visions® PV 8.2 Intravascular Ultrasound Imaging Catheter

Date Prepared: June 14, 2007

AUG 3 1 2007

Submitted by: Volcano Corporation
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Contact person: Jennifer Motto, RAC
Regulatory Affairs Specialist

Phone number: (916) 231-4509
Facsimile number: (916) 638-2647

Device Name: Visions® PV 8.2F Intravascular Ultrasound Imaging Catheter

Classification name:	**Class**
• 870.1200 Diagnostic Intravascular catheter	II

Predicate Device:

The Visions® PV 8.2F Intravascular Ultrasound Imaging Catheter is substantially equivalent to the predicate device, Visions 8.2F PV Catheter cleared under K982329 on January 14, 1999.

Device Description:

The Visions PV 8.2F catheter incorporates a cylindrical ultrasound transducer array. The array radiates acoustic energy into the surrounding tissue and detects the subsequent echoes. The information from the echoes is used to generate real-time images of the peripheral vessels.

The Visions PV 8.2F catheter utilizes an internal lumen that allows the catheter to track over the 0.038" (0.97 mm) guide wire. The Visions PV 8.2F catheter is introduced percutaneously or via surgical cutdown into the vascular system.

The Visions PV 8.2F, Catalog Number 88900, catheters may be used with the In-Vision Imaging System (K031148, cleared 05/28/2003), the Volcano s5 Imaging System (K051920, cleared 08/19/2005), and the Volcano s5i Family of Imaging Systems K061215, cleared 08/10/2006).

Intended Use:

The Visions PV 8.2F catheters are designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature by providing a cross-sectional image of such vessels. The Visions PV 8.2F ultrasound imaging catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures and dimensional measurements from the image.

Device Technological Characteristics and Comparison to Predicate Device:

The Volcano Corporation Visions PV 8.2F Intravascular Ultrasound Imaging catheter is substantially equivalent to the predicate device, Visions 8.2F PV Intravascular Ultrasound Imaging Catheter cleared under K982329 on January 14, 1999. Modifications include changes to the material used in some components of the catheter and a change in the shelf life of the device.

The modified Visions PV8.2F Intravascular Ultrasound Imaging Catheter uses the same fundamental scientific technology and has the same intended use as that of the predicate device.

Performance Data:

Applicable testing was performed in accordance with the Validation Test Report and the Risk Analysis was reviewed to assess the impact of the change in materials to the device. The new material was tested for biocompatibility according to ISO 10993-1 and the results met the acceptance criteria. Shelf life testing of the device was performed due to this change in materials.

Conclusion:

The Visions PV8.2F Intravascular Ultrasound Imaging Catheter has the same performance specifications, fundamental scientific technology and intended use as that of the predicate device, Visions 8.2F PV Catheter, cleared under K982329 on January 14, 1999. Modifications to the device do not raise any new questions regarding safety or efficacy. The performance data and a declaration of conformity with design controls support a determination of continuing substantial equivalence of the subject device to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2007

Volcano Corporation
c/o Ms. Jennifer Motto, RAC
Regulatory Affairs Specialist
2870 Kilgore Road
Rancho Cordova, CA 95670

Re: K071660
Visions® PV 8.2F Intravascular Ultrasound Imaging Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Intravascular Ultrasound Catheter
Regulatory Class: Class II (two)
Product Code: OBJ
Dated: August 7, 2007
Received: August 9, 2007

Dear Ms. Motto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071660

Device Name: Visions® PV 8.2F Intravascular Ultrasound Imaging Catheter

Indications for Use:

The Visions PV 8.2F catheters are designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature by providing a cross-sectional image of such vessels. The Visions PV 8.2F ultrasound imaging catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures and dimensional measurements from the image.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071660